APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER

ART UNIT	PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _29 May 2001_ .

2a)☒ This action is **FINAL.**   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _13 and 15-30_ is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _13 and 15-30_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

    If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____ .

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

    a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)		4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)		5) ☐ Notice of Informal Patent Application (PTO-152)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .		6) ☐ Other: .

1.   Receipt is acknowledged of Applicant's amendment and response filed May 29,

2001. Claim 14 has been cancelled and new claims 21-30 have been added.

Accordingly, claims 13 and 15-30 are pending and are examined in the instant

application.

2.   Any pertinent recitations of the statutes applicable to this Office Action may be

found in the precious Office Action.

Specification

3.   Applicant is required to update the status of all parent priority applications in the

first line and elsewhere of the specification. It is noted that the status of SN 07/971,951

has not yet been updated. This application has matured into U.S. Patent 5, 639,947.

Correction is required.

Drawings

4.   This application has been filed with informal drawings which are acceptable for

examination purposes only. Formal drawings will be required when the application is

allowed.

Claim Rejections - 35 USC § 112

5.   The rejection of claims 16, 18 and 18 under 35 U.S.C. 112, second paragraph,

as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention has been overcome by Applicant's

amendments and is hereby **withdrawn**.

6.   The rejection of claims 13-20 under 35 U.S.C. 112, first paragraph, because the

specification, while being enabling for an immunoglobulin molecule which binds <u>and</u>

neutralizes a preselected ligand and an immunologically active fragment thereof (immunogenic epitope of the native protein), does not reasonably provide enablement for an immunoglobulin molecule which simply finds to a preselected ligand and a "fragment thereof" without immunological activity, has been obviated by Applicant's amendments and is hereby **withdrawn**.

Claim Rejections - 35 USC § 102

7.   Claims 13 and 15-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Stolle et al. (US Pat. No. 4748018), for the reasons set forth in the previous Office Action, paragraph 8.

Applicant's arguments with regard to this rejection have been fully considered, but were not found persuasive. Applicant emphasizes that the antibodies used in their passive immunization process are produced in plants, whereas Stolle's antibodies are not produced in plants. Applicant states that their antibodies are not induced by an endogenous immune response to an antigen since they are produced in plants. These arguments were not found persuasive.

The mere fact that Applicant's antibodies are produced in plants does not in itself distinguish the instant method over that of Stolle. Applicant must show that, by their production in plants, Applicant's antibodies are structurally different from those of Stolle. The previous Office Action indicated this fact when it set forth that the antibodies of Stolle inherently are free of sialic residues <u>absent evidence to the contrary</u>. Moreover, though Applicant uses antibodies produced in plants, it is important to note that the DNA used to transform those plants was isolated from a source that expressed that antibody,

the source being one that was induced to express the antibody from the DNA by endogenous immune response to an antigen. Further, the claims do not exclude such a process as the source for their transforming DNA.

Accordingly, the claims are anticipated by Stolle et al.

Claim Rejections - 35 USC § 103

8.   Claims 13 and 15-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al. (US Pat. No. 4956282) and the During dissertation (Univ. of Koln, FRG, English translation, July 9, 1988) in view of Stolle et al. (US Pat. No. 4748018), for the reasons set forth in the previous Office Action, paragraph 10.

Applicant's arguments with regard to this rejection have been fully considered, but were not found persuasive. Specifically, Applicant asserts that Goodman does not describe the expression of immunoglobulins sufficiently to allow one to make such in plants. Applicant states that Goodman does not teach cleavable leader sequences which are essential to the production of immunologically active immunoglobulin molecules. Thus, Applicant concludes that Goodman merely provides an invitation to experiment.

Applicant further assert that During suffers from these same problems and faults During for poor experimental success. In addition, Applicant concludes that During did not teach plant cell secretion since no association of antibody with the cell wall is observed.

Finally, Applicant reiterates that Stolle is silent with regard to the production of antibodies and plants. Therefore, Applicant concludes that Stolle does not remedy the deficiencies noted in Goodman and During.

These arguments have been fully considered, but were not found persuasive. Initially, the Office notes that the claims are directed to a method of passive immunization. No evidence has been provided which definitively shows that antibodies produced in plants by Applicant's process will be structurally different from the antibodies of the prior art. Moreover, the Office also notes that only claims 29 and 30 require the immunoglobulin to be a complete, assembled antibody. Thus, the immunoglobulin molecule reads on only fragments of the fully-assembled antibody. Since much of Applicant's objections to Goodman are directed to this issue, for most of the instant claims, these objections are not commensurate in scope with the claims.

With regard to the teaching of During, the Office notes that the strategy of During was successful. The standard for obviousness is not commercial success, but technical success. In other words, did During produce antibodies in plants? Based on a careful reading of During, the Office concludes the answer to be yes. During states that antibody was produced albeit in very low quantities. Nothing in the current claims distinguishes over During in the production of these antibodies such that one would be able to produce antibodies following Applicant's claimed process in quantities unexpectedly better than by following During's process. Again, it is important to reiterate that the instant claims do not require the production of heavy and light chains fully-assembled into complete antibodies.

Accordingly, the instant claims would have been *prima facie* obvious over the

applied prior art.

Conclusion

9.   **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time

policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the mailing date of this final action.

10.   No claim is allowed.

11.   Papers relating to this application may be submitted to Technology Sector 1 by
facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using
fax number (703) 308-4242. All Technology Sector 1 fax machines are available to
receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such
papers must conform with the Notice published in the Official Gazette, 1096 OG 30,
(November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Bui whose telephone number is (703) 305-1996. The Examiner can normally be reached Monday-Friday from 6:30 AM - 4:00 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Phuong Bui
Primary Examiner
Group Art Unit 1638
August 12, 2001

PHUONG T. BUI
PRIMARY EXAMINER